

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

H. LUNDBECK A/S, TAKEDA  
PHARMACEUTICAL COMPANY LTD.,  
TAKEDA PHARMACEUTICALS U.S.A.,  
INC., TAKEDA PHARMACEUTICALS  
INTERNATIONAL AG, and TAKEDA  
PHARMACEUTICALS AMERICA, INC.,

Plaintiffs,

V.

APOTEX INC., et al.,

Defendants.

C.A. No. 18-88-LPS

CONSOLIDATED

**REDACTED VERSION**

**FILED MAY 13, 2020**

**LETTER TO THE HONORABLE LEONARD P. STARK FROM JAMES M. LENNON  
REGARDING DEFENDANTS' MOTION TO STRIKE PORTIONS OF  
PLAINTIFFS' EXPERT REPORTS TO LUPIN**

Dated: May 6, 2020

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*Attorneys for Defendants Lupin Limited and  
Lupin Pharmaceuticals, Inc.*

Dear Chief Judge Stark:

Defendants Lupin Limited and Lupin Pharmaceuticals, Inc. (collectively, “Lupin”) respectfully move to strike portions of Plaintiffs’ expert reports served on April 16, 2020. By email dated April 8, 2020—*only one week before expert reports were due* and one month after the service of Plaintiffs’ self-termed Final Infringement Contentions—Plaintiffs first informed Lupin of their intention to assert new patent claims directed to the [REDACTED]. The [REDACTED] was never previously asserted against Lupin. And, Lupin’s litigation strategy followed that course. This untimely and suspect theory—that Lupin’s ANDA products somehow contain the [REDACTED] blindsides Lupin and undermines the very purpose of adequate disclosures during the course of litigation.<sup>1</sup> It should be stricken.

## I. Background

This Hatch-Waxman action commenced on January 12, 2018, with Plaintiffs asserting infringement of three polymorph patents directed to crystal forms of vortioxetine hydrobromide (Case No. 18-90, D.I. 1). Plaintiffs later filed a separate action asserting infringement of a related polymorph patent (Case No. 18-777, D.I. 1). Thereafter, Plaintiffs sought leave to assert two additional method of treatment patents, and one process patent. This Court granted leave on May 29, 2019 (D.I. 260). A total of seven patents are asserted against Lupin.

A number of dates are relevant here: Lupin produced its ANDA to Plaintiffs on July 25, 2018 (*21 months ago*). Lupin produced samples of both its proposed ANDA product and the API used therein in early October 2018 (*18 months ago*). Substantial completion of document production occurred on August 30, 2019 (*8 months ago*). All depositions of Lupin witnesses were completed in December 2019 (*4 months ago*).

Plaintiffs served Initial Infringement Contentions on September 28, 2018, and asserted claims [REDACTED] of the ’630 patent. Dependent claims [REDACTED]. Ex. 1 (Pltfs’ Initial Infringement Contentions (incl. Exs. A and D)) at D-1 – D-12. Plaintiffs served a second set of Initial Infringement Contentions on July 12, 2019 directed to those patents added by amended complaint, but did not supplement their other contentions at the time. Plaintiffs served Final Infringement Contentions on March 6, 2020, adding [REDACTED] of the ’630 patent and identifying “[REDACTED]” Ex. 2 (Pltfs’ Final Infringement Contentions (incl. Exs. A and D)) at D-7.<sup>2</sup> At this point, fact discovery closed and Lupin was never informed of Plaintiffs’ [REDACTED]. Instead, Plaintiffs’ theory was limited to the [REDACTED].

On April 8, 2020, however, Plaintiffs stated by email, for the first time, that claims [REDACTED] would be asserted against Lupin. Ex. 3 (Email from [REDACTED]).

<sup>1</sup> To make matters worse, this is not the first time Plaintiffs have sought to expand the scope of the case, whether by amended Complaint or otherwise. And, while the Court ultimately permitted the first amendment, and has been briefed on yet another (D.I. 727), there is no justification for allowing Plaintiffs yet a further opportunity to expand the case and advance their moving target approach with respect to an infringement theory.

<sup>2</sup> Plaintiffs similarly identified “[REDACTED]”, but not *gamma*) when specifying their infringement theory for a separate polymorph patent. Exhibit 2 at A-3.

A. Schmitt). Plaintiffs did not serve contentions detailing this new theory. Plaintiffs opening reports were served on April 16, 2020, and included allegations related to the [REDACTED]—the *first time* this theory was ever disclosed to Lupin. However, as Plaintiffs’ reports indicate, testing was performed on Lupin’s samples as early as May 5, 2019 and concluded by December 1, 2019. Ex. 4 (Appx. C to Expert Report of Dr. Morin). With this data in hand, in some instances *since May 2019*, Plaintiffs withheld disclosure of their [REDACTED] theory until serving opening reports.

## II. Legal Standard

Untimely infringement theories should be stricken “unless the party’s violation was substantially justified or is harmless.” *Intellectual Ventures I LLC v. AT&T Mobility LLC*, No. 13-1668-LPS, 2017WL658469, \*1 (D. Del. Feb. 14, 2017) (Stark, C.J.). This Court considered six *Pennypack* factors in this analysis: (1) the importance of the information withheld; (2) the prejudice or surprise to the party against whom the evidence is offered; (3) the likelihood of disruption of the trial; (4) the possibility of curing the prejudice; (5) the explanation for the failure to disclose; and (6) the presence of bad faith or willfulness in not disclosing the evidence. *Id.* (citing *Meyers v. Pennypack*, 559 F.2d 894, 904-05 (3rd Cir. 1977)).

## III. The *Pennypack* Factors Favor Striking Plaintiffs’ New Infringement Theory

“Opening expert reports are not the appropriate time to disclose new infringement allegations.” *TQ Delta, LLC v. ADTRAN, Inc.*, Nos. 14-954-RGA, 15-121-RGA, 2019 WL 4346530, \*2 (D. Del. Sept. 12, 2019); *see also Galderama Labs. LP et al. v. Amneal Pharmaceuticals LLC et al.*, No. 16-207-LPS, D.I. 203 (D. Del. Nov. 29, 2017) (Stark, C.J.) (granting motion to strike contentions not timely disclosed). This is not a situation where contentions were supplemented to identify additional evidence supporting existing theories. Rather, Lupin now faces new allegations that were *never before disclosed*. The *Pennypack* factors favor exclusion here.

**Factor 1:** The [REDACTED] is but one of the [REDACTED] Plaintiffs now allege Lupin’s ANDA Product contains. Striking this new theory would not otherwise impact their assertion regarding the [REDACTED], nor would it remove any patents or patent claims that were timely asserted during the discovery period. In stark contrast, the withheld information carries great importance to Lupin, as it constitutes a brand new theory improperly disclosed for the first time in opening expert reports. Accordingly, this factor favors exclusion.

**Factor 2:** The “prejudice or surprise” to Lupin heavily favors exclusion in this case. As early as September 28, 2018, Plaintiffs notified Lupin in their Initial Infringement Contentions that they “expect that testing of samples and expert testimony” will support their allegations of infringement. Ex. 1 at D-8. Lupin produced samples to Plaintiffs for testing immediately thereafter, in October 2018. Testing by Plaintiffs’ expert commenced May 5, 2019 and concluded by December 1, 2019. Ex. 4. Yet, Plaintiffs withheld this new theory until opening expert reports.

Prejudice is clearly present as well. Had Plaintiffs timely disclosed this new infringement theory, Lupin would have had a fair opportunity to formulate its discovery strategy. Plaintiffs produced approximately *two million pages* of documents in this case. Reviewing those for issues related to the [REDACTED], including the form’s conception, reduction to practice, analytical data, and correspondence characterizing the same, is a mountainous endeavor that Lupin was unfairly led to

believe was unnecessary.<sup>3</sup> Instead, as a result of Plaintiffs' willful delay, Lupin is now forced to rebut this new theory in expert discovery with limited resources in an effort to preserve an expert opinion if the Court allows this theory into the case. Accordingly, the surprise and prejudice to Lupin heavily favors exclusion. *See TQ Delta*, 2019 WL 4346530, \*2 (finding prejudice and surprise where infringement theory was first disclosed in expert reports).

**Factor 3 and 4:** The prejudice to Lupin cannot be cured without disrupting the case schedule. A delay of these proceedings is itself prejudicial inasmuch as it could delay entry of Lupin's generic product on the market and provide Plaintiffs a windfall by keeping competitors out of the market—all resulting from their untimely disclosure of a new infringement theory. As noted above, discovery could have taken a different course. Instead, fact discovery has long been closed, Lupin is forced to rebut eight separate opening expert reports from Plaintiffs, with expert discovery set to close on August 21, 2020, and trial is five months away. Accordingly, these factors heavily favor exclusion. *See TQ Delta*, 2019 WL 4346530, \*2 (granting motion to strike filed 5 months before trial); *Galderama*, D.I 203 (same).

**Factor 5:** Plaintiffs represented in correspondence that they “notified Lupin as soon as we understood that the testing data supported Lupin's infringement of [REDACTED]” Ex. 5 (Email from M. Hare). This is, at best, a play on words. Plaintiffs had data supposedly supporting their infringement allegations as early as May 5, 2019. To suggest Plaintiffs first “understood” the data collected nearly a year earlier is not a justifiable “explanation for the failure to disclose.” *See Galderama*, D.I 203 (finding this factor favored exclusion where untimely contentions were served 5 months after Plaintiffs received certain dissolution data critical to new infringement theory). This factor also weighs in favor of exclusion.

**Factor 6:** Plaintiffs served initial contentions on September 28, 2018, and did not articulate any theory that Lupin's ANDA products contain the [REDACTED]. Nor did they assert any claims specifically claiming the [REDACTED]. As Plaintiffs' expert report details, by June 11, 2019, approximately half of the testing on Lupin's samples had been completed. On July 12, 2019, Plaintiffs served contentions related to the patents added by amended complaint, but chose not to supplement their prior contentions to identify their new theory. Then, on March 6, 2020, Plaintiffs specifically identified only the [REDACTED] as forming the bases for their infringement theory, despite being in possession of the testing results purportedly needed to allege the presence of the [REDACTED]. Plaintiffs could have placed Lupin on notice of this theory at a number of different stages of this case. But, they didn't. Therefore, this factor also favors exclusion.

Just as in *Galderama*, Plaintiffs never even provided a “hint they might eventually assert” this new theory. *Id.*, D.I. 203. They had everything they now rely on to support this suspect theory, but chose to wait. Whether their refusal to disclose this theory was intentional, or the product of willful blindness to their own test results, is irrelevant. The extraordinarily late disclosure of this theory is neither justified nor harmless. Lupin therefore requests that any expert opinions relating to, or alleging the presence of, the [REDACTED] in Lupin's ANDA products be stricken.

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<sup>3</sup> The invalidity case could have also been different. With little time, Lupin was forced to adopt the opinions on these claims set forth in the invalidity report jointly served with other Defendants, and which were only included because Plaintiffs chose to assert them against at least one defendant well before Lupin. Due to Plaintiffs' dilatory tactics, Lupin was unable to independently consider, investigate or develop any additional invalidity defenses to these claims.

Respectfully submitted,

/s/ James M. Lennon

cc:

Clerk of Court (via CM/ECF)

All Counsel of Record (via e-mail)